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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/889,053 | 03/13/2003 | Thomas Woods Keough | 7379M | 6283 |

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EXAMINER

WHALEY, PABLO S

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/889,053 | KEOUGH ET AL. | |
| | Examiner | Art Unit | |
| | Pablo Whaley | 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 8-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>Jan. 28, 2002</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

APPLICANTS' ELECTION

Applicants' election with traverse of Claims 1-7 and Species 1A drawn to MALDI PSD, filed 11/14/2005, is acknowledged. Applicants' arguments regarding lack of burden of search upon examining Claims 1-7 and Claims 8-10 together have been found to be unpersuasive. The burden of search is maintained as the examination process requires a search of non-patent literature, U.S. patent publications, U.S. patents, as well as foreign patent literature. Claims 8-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/14/2005.

CLAIMS UNDER EXAMINATION

Claims herein under examination are Claims 1-7.

CLAIM REJECTIONS - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1, step (a), recites the limitation "derivatizing the..polypeptide...with one or more acidic moieties having pKas of less than 2, when coupled with the polypeptide." Applicant has described acidic moiety reagents (Specification, p.8), however it is unclear how "acid moieties" alone can derivatize polypeptides. As written, it is unclear what is coupled to the polypeptide. As written, it is further unclear whether the derivatized polypeptide or the polypeptide coupled with something has a pKa of less than 2.

Claim 1, step (a), recites the limitation "pKas of less than 2". The pKa value is determined by the dissociation constant, which is a function of pH. Therefore, this limitation is meaningless without information related to pH.

Claim 3 recites the limitation "commercially available software." Applicant is reminded that commercially available products are not proper subject matter for patentability. Clarification is requested via clearer claim language.

Claim 5 recites "a method...characterized in the peptides...are produced by digestion. It is unclear if this is an actual method step or intended to be a further limitation of the peptides of claim 1. If the latter, then it is further unclear what limitation of the structure, sequence, etc. is intended by the method of producing the polypeptides.

CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, and 5 are rejected under 35 U.S.C. 102 (b) as being anticipated by Knierman et al. (Rapid Communication in Mass Spectrometry, 1994, Vol. 8, 1007-1010)

Knierman et al. teach methods by which a sequence-dependent peptide fingerprint can be rapidly obtained upon partial hydrolysis of peptides with HCl and subsequent analysis with MALDI (Abstract). More specifically, Knierman et al. teach the following aspects of the instantly claimed invention:

- N-terminus derivatization of peptides (Abstract), as in instant claim 1.
- Digestion of peptides was carried out with trifluoroacetic acid and HCl (p.1007, col. 2, lines 8-12), which correlates to acidic moieties of pKas of less than 2, as in instant claims 1 and 5.
- Obtaining sequence-dependent 'fingerprints' for peptides (Abstract), which correlates to a "fragmentation pattern" as in instant claim 1.
- Digestion of synthetic peptides with 3M HCl (Abstract), which correlates to "polypeptides" as in instant claims 4 and 5.
- Potential use of a database to confirm identification of a protein by MALDI analysis (p. 1010, col. 1, lines 20-21).
- Mass spectrometry of peptides using MALDI.

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Claims 1-7 are rejected under 35 U.S.C. 102 (a) and (e) as being anticipated by Hillenkamp et al. (US PAT: 6,558,902, Priority Date: May 7, 1998).

Hillenkamp et al. teach processes for analyzing biological macromolecules using MALDI (Abstract). More specifically, Hillenkamp et al. teach the following aspects of the instantly claimed invention:

- Determining the sequence of a target biological macromolecule (i.e. polypeptide) by treating the biological macromolecule with an agent that cleaves unilaterally from a terminus and identifying the released monomer subunits by IR-MALDI mass spectrometry (Col. 47, lines 35-40), as in instant claim 1.
- Biological agents (e.g. enzymes) and chemical agents in the presence of acid (e.g. Edman's reagent) to cleave terminal amino acids (Col. 16, lines 63-66, and Col. 17, lines 8-10), as in instant claim 1.
- Method for determining the sequence of at least one species of polypeptide (Claims 169, 172), as in instant claim 1.
- Use of MALDI-PSD mode for analysis (Col. 93, lines 10-15), as in instant claim 2.
- Analyzing polypeptide fragments using IR-MALDI and determining their sequence, which correlates to analyzing and interpreting the fragment pattern (Col. 14, lines 36-55, Fig. 1), as in instant claims 1 and 2.
- Determination of mass of peptide fragments using a database (Col. 60, lines 1-7), as in instant claim 3.
- Genetically engineered polypeptides (Col.17, lines 20-25), which correlates to synthetic polypeptides, as in instant claim 5.
- Generating polypeptide fragments through enzymatic digestion at the N-terminus (Claims 169, 170, 172), as in instant claims 1, 5, and 6.

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- Sulfonic acid used in the process of analyzing a polypeptide (Col. 19, lines 27-37), which correlates to an 'acidic moiety' as in instant claim 7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following prior art publications are the basis for executing this rejection:

Claims 1, 2, and 4-6 are rejected under 35 U.S.C. are rejected under 35 U.S.C. 103(a) as being anticipated by Knierman et al. (Rapid Communication in Mass Spectrometry, 1994, Vol. 8, 1007-1010), in view of Roth et al. (Mass Spectrometry Reviews, 1998, 17, 255-274).

Knierman et al. teach methods by which a sequence-dependent peptide fingerprint can be rapidly obtained upon partial hydrolysis of peptides with HCl and subsequent analysis with MALDI, as discussed previously.

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Knierman et al. do not specifically teach the use of MALDI-PSD for peptide analysis or the use of enzymatic digestion.

Roth et al. teach the use of MALDI-PSD mass spectrometry for peptide analysis (Fig. 7, p. 263), as in instant claim 2. Roth et al. also teach the use of acids or enzymes to digest peptides, generating peptide derivatives (p. 259, col. 2, lines 40-46), as in instant claim 6.

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the invention of Knierman et al. with the use of MALDI-PSD as taught by Roth et al., where the motivation would have been to improve the fragmentation pattern of derivatized peptides (Roth et al, p. 259, lines 25-30), and with the use of enzymatic degradation of peptides as taught by Roth, where the motivation would have been to avoid derivatization of side-chains (p. 265, col. 2, lines 48-50), resulting in the practice of the instant claimed invention with a reasonable expectation of success.

Double Patenting Rejection

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321 (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

Claims 1-3, 5, and 6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5, and 10 of co-pending Application No. 09/863,786. Reference claims 1 and 2 correlate to instant claim 1, reference claim 3 correlates to instant claim 2, reference claim 5 correlates to instant claim 3, and reference claim 10 correlates to instant claims 5 and 6. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the broadly encompassing scope of the instantly claimed invention, thus the inventions have overlapping embodiments.

Co-pending Application No. 09/863,786 does not teach the limitation of MALDI-PSD. However, Roth et al. teach methods of peptide analysis using MALDI-PSD (see above).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have combined the invention of the co-pending Application No. 09/863,786 with Roth et al., where the motivation would have improve the fragmentation pattern of derivatized peptides (Roth et al, p. 259, lines 25-30).

CONCLUSION

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
1/9/06